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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,344	04/08/2004	Rajagopal Bakthavatchalam	N00.2100C2	8155

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EXAMINER	
SACKEY, EBENEZER O	
ART UNIT	PAPER NUMBER
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,344	BAKTHAVATCHALAM ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50* is/are allowed.

6)☒ Claim(s) *48-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-47 have been cancelled.

Claims 48-67 are pending.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants may need to update the oath or Declaration to complete the status of Application number 10/385,973 now patent number 6,753,336.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 06/30/04 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-49 and 51-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for obesity, does not reasonably provide enablement for treating sexual disorders and bulimia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the pharmaceutical composition to treat such diverse diseases commensurate in scope with these claims. The claims, insofar as they embrace treating bulimia, an orgasmic or psychogenic impotence are not enabled.

The claims above, recite instructions for using a packaged pharmaceutical composition for treating various diseases i.e., packaged pharmaceutical compositions for treating disorders responsive to melanin concentrating hormone receptor modulators. However, Kowalski et al., (provided herein) teaches the role of MCH-1 signaling in the regulation of energy homeostasis and thus, has led to the treatment of obesity.

Therefore, the specification is not adequately enabled for the scope of MCH binding to MCH 1 receptor embraced by the claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is the use of packaged pharmaceutical compositions that are useful as inhibitors of MCH binding to MCH 1 receptors. As stated however, the claims are not enabled for the treatment of any of the cited diseases. Although there are some lifestyle modifications, which may have a profound impact upon diseases and complications associated with MCH binding, to date, there are no known chemotherapeutic agents recognized in the art for the conditions caused by the modulation of melanin concentrating hormone receptors.

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art involves screening *in vitro* and *in vivo* system to determine which compounds exhibited the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any prophylactic regimen on its face.

The instantly claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833,166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue.

It is the state of the art that there is no known packaged pharmaceutical composition for the recited diseases. The specification provides no guidance as to what diseases are being treated by the instant pharmaceutical package. The notion that a phenyl-2-aminomethylcyclopropanes of formula (I), have such a range of uses is not seen to be supported in the art at the time of applicants' effective filing or even in the present. While phenyl-2-aminomethylcyclopropanes of formula (I) are known for treating obesity, there is no evidence of record that there is a correlation of success for treating any of the other diseases by inhibiting MCH binding MCH receptor. The long list of alleged treatable diseases constitutes "an invitation to experiment" which is not in compliance with 35 USC 112. Note Kowalski et al., (provided herein) which teaches the role of MCH-1 signaling in the regulation of energy homeostasis and hence, has led to the treatment of obesity.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would need to determine which of the pharmaceutical compositions of claim 48 would posses the activity necessary to treat diseases associated with the inhibition of MCH binding MCH receptor.

4) Level of predictability in the art.

The art pertaining to the treatment of various diseases remains highly

unpredictable. As disclosed above, there is no absolute predictability even in view of the seemingly high level of skill in the art. Many of the symptoms of the diseases may be treated, however, applicant has failed to provide sufficient evidence or to point out treatable measures recognized in the art at the time the invention was made.

5) Amount of direction and guidance provided by the inventor.

The amount of direction or guidance present is found on page 5 of the specification where the activities of the pharmaceutical package are provided. However, there is no clinical data or scientific data in the specification to controvert the findings in the art from which one can reasonably conclude that all of applicants' compounds possess all the uses claimed herein. Where the assertion of utility is unusual, difficult to treat or speculative, the Examiner has the authority to require evidence that tests relied on are reasonably predictive of *in vivo* efficacy by those skilled in the art. See for example *In re Ruskin*, 148 USPQ, *EX parte Jovanovics*, 211 USPQ 907. Also note MPEP .2164.05(a).

6) Existence of working examples.

As discussed above, working example is found on page 5 of the specification where the activities of the pharmaceutical compositions are provided. Applicant's limited example does not enable one of ordinary skill in the art to treat the numerous amounts of diseases encompassed by the instant invention. At best, the treatment currently asserted for the instant invention is the treatment of obesity and not the treatment of any of the other diseases as note Kowalski et al.

7) Breadth of claims.

Additionally, claim 48 is extremely broad due to the vast number of possible diseases encompassed by the instant claim language.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Hence, the specification fails to provide sufficient support of the broad use of the pharmaceutical package of claim 48 for the treatment of eating disorders or sexual disorders. As a result necessitating one of ordinary skill in the art to perform an exhaustive search for which disease can be treated by the compositions of claim 48 in order to practice the claimed invention.

Genentec Inc. V. *Novo Nordisk A/S* (CAFC) 42 USPQ 2D 1001, states that:

"a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which diseases of claim 48 can be treated by the pharmaceutical package encompassed in instant claim 48 with no assurance of success.

This rejection can be overcome by limiting the treatable disease to obesity in the claim language.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 53, line 2; ---anorgasmic--- should be "an orgasmic".

Claim 56 recites the limitation "W is nitrogen" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-67 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-29 and 30 of U.S. Patent number 6,753,336. Although the conflicting claims are not identical, they are not patentably distinct from each other because the prior art teaches the use of the

compositions in treating obesity whereas the instant claims are drawn to treating, sexual disorders and eating disorders. However, the mechanism of action in the prior art claims in parent patent number 6,753,336, which is relied on to practice the instant invention is similar. Thus, the prior art differs from instant invention in the scope of treatable diseases with the pharmaceutical compositions. Note *Eli Lilly* v. *Barr* 58 U.S.P.Q. 2d. 1869 at 1880, which is on point here.

One of ordinary skill in the art would have found the claimed uses *prima facie* obvious over the cited art, since the reference mechanism of action is similar and employs similar pharmaceutical compositions. The requisite motivation for arriving at the claimed compositions stems from the fact that the instant invention and the prior art both employ similar mechanisms to treat various disease states Again note that the disclosed compositions have activity as agents for pharmaceutical use, thus the skilled artisan would expect such structurally similar compositions to posses similar properties. Additionally, the Court stated in In re Payne et al., 606 F.2d 302, 203 USPQ at 255 (CCPA 1979):

"the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound."

Furthermore, any question of why would one conceive and use the similar compounds (i.e., motivation) is answered by the Court in In re Gyurik et al., 596 F.2d 1012, 201 USPQ 552 at 557:

"In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the prima facie case of obviousness, rises from the expectation that compounds similar in structure will have

similar properties" in pharmaceutical industry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
April 11, 2007

James O. Wilson
Supervisory Patent Examiner
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Technology Center 1